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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CIVIL ACTION NUMBER:

IN RE: VALSARTAN PRODUCTS
LIABILITY LITIGATION

19-md-02875
CASE MANAGEMENT CONFERENCE
via Teams

Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets
Camden, New Jersey 08101
January 4, 2024
Commencing at 1:15 p.m.

B E F O R E:
THE HONORABLE ROBERT B. KUGLER
UNITED STATES DISTRICT JUDGE
and
THOMAS I. VANASKIE (RET.)
SPECIAL MASTER

A P P E A R A N C E S:

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For the Plaintiffs

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Proceedings recorded by mechanical stenography; transcript
produced by computer-aided transcription.

1 **A P P E A R A N C E S (Continued):**

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28 **ALSO PRESENT:**

29 LORETTA SMITH, ESQUIRE
30 Judicial Law Clerk to The Honorable Robert B. Kugler
31 Larry MacStravic, Courtroom Deputy

1 (PROCEEDINGS held via Teams before The Honorable
2 ROBERT B. KUGLER and SPECIAL MASTER THOMAS I. VANASKIE at
3 1:15 p.m.)

4 THE COURT: Is Mr. Harkins on this call?

5 MR. HARKINS: Yes, Your Honor, I'm here.

6 THE COURT: Let's talk about your orders to show
7 cause.

8 All seven of them have been resolved apparently --
9 well, not resolved. Three, you have withdrawn the Pauline
10 Harris, Hines and Kaluhiokalani cases. Correct?

11 | MR. HARKINS: Three can be withdrawn.

12 THE COURT: Then you're going to carry the other
13 four; Alexandra Samocha; Benjamin Andrews; Haughton,
14 H-A-U-G-H-T-O-N; and Kennedy. Correct?

15 MR. HARKINS: That's correct.

16 THE COURT: You have two orders to show cause you
17 want for next time, Davidson and Mantalis.

18 Any change on those?

19 MR. HARKINS: No updates there, Your Honor. The
20 defendants would request orders to show cause returnable at
21 the next case management conference in both of those two
22 cases.

23 THE COURT: Anybody have any objection to listing
24 these for an order to show cause?

25 | (No response.)

1 THE COURT: Okay. Hearing none, they will be set for
2 the next conference.

3 And you did not have a chance to list any new first
4 listings, you'll do that the next conference. Correct?

5 MR. HARKINS: Correct, Your Honor.

6 THE COURT: Anything else you want to bring up?

7 MR. HARKINS: Nothing from the defense on those.

8 THE COURT: Okay. Thank you.

9 Now, you have -- go back to the letters from counsel.

10 The fact sheet, have you had any further -- as to the
11 fact sheet for the losartan/irbesartan cases?

12 MR. GEOPPINGER: Good afternoon, Your Honor. Jeff
13 Geoppinger on behalf of the defendants.

14 I'm sorry, I didn't quite hear your question with
15 respect to the fact sheet.

16 We are negotiating it. We've made substantial
17 progress. And we're just looking for the Court to provide us
18 a time to address with Judge Vanaskie any disputes that may
19 remain on the fact sheet within the next 30 days or so.

20 THE COURT: Is Judge Vanaskie on this call somewhere?

21 SPECIAL MASTER VANASKIE: Yes. I'm on. I'm on, Your
22 Honor.

23 THE COURT: How are you doing, Tom?

24 SPECIAL MASTER VANASKIE: Good. How are you doing?

25 THE COURT: Good.

1 Do you want to set a date you want to hear that?

2 SPECIAL MASTER VANASKIE: Yeah.

3 How much time do counsel anticipate they need to
4 submit letter briefs, and do they want to go one side at a
5 time? Mr. Geoppinger?

6 MR. GEOPPINGER: I think that that would be fine,
7 Your Honor. The defendants, I believe we can submit
8 initially, and then the plaintiffs submit a response. And I
9 don't know, I think previously we've had a very short reply
10 provided for when we did this previously in the valsartan
11 case, so I would suggest we just follow that same model.

12 And with respect to timing, working backwards from
13 the defendants' perspective, I was looking at the week of the
14 22nd of this month for -- to hear the issues. So if we can
15 find a date during that week, we can work backward on the
16 filing dates on the briefs, letter briefs.

17 SPECIAL MASTER VANASKIE: All right. Let me look at
18 my calendar.

19 How would the 24th of January be? It's a Wednesday.

20 MR. GEOPPINGER: That would work for the defendants,
21 Your Honor.

22 SPECIAL MASTER VANASKIE: Who is addressing this
23 issue for the plaintiffs?

24 MR. KASS: Your Honor, Zalman Kass on behalf of the
25 plaintiffs.

1 If it were possible to do the following week, it
2 would work a lot better, but I understand that there are other
3 factors involved. But if not, I will -- we'll make it work,
4 the 24th.

5 SPECIAL MASTER VANASKIE: It's a little more
6 problematic for me to --

7 MR. KASS: We'll make it work then.

8 SPECIAL MASTER VANASKIE: All right. So we'll
9 schedule hearing/argument for January 24th at 1:00 p.m., if
10 that's all right.

11 Larry, if we could impose upon you to do it by Teams,
12 let's do it with the Teams format.

13 All right. So working backwards, can we have the
14 defense opening brief or opening submission by the 11th of
15 January? Mr. Geoppinger?

16 MR. GEOPPINGER: Would the Court -- would the Court
17 be -- I have another brief due that day on --

18 Would you be flexible, Your Honor, could we submit it
19 on -- and obviously with the plaintiffs' counsels' agreement
20 here -- on the 15th?

21 I know that's a court holiday.

22 Would the 16th be too late?

23 MR. KASS: On the plaintiffs' side it would depend on
24 when our opposition would be due. Right? It doesn't give
25 much room.

1 SPECIAL MASTER VANASKIE: Can we dispense with the
2 reply and have the 16th as the defense submission, the 23rd as
3 the plaintiffs' submission?

4 MR. GEOPPINGER: That's fine by -- I'm all -- you
5 know, I will agree, that's fine with the defendants, Your
6 Honor.

7 SPECIAL MASTER VANASKIE: I mean, you'll have an
8 opportunity to reply then when we hear it on the 24th. All
9 right?

10 MR. KASS: Okay.

11 SPECIAL MASTER VANASKIE: So let's go with the 16th
12 for the defense submission, the 23rd for the plaintiffs'
13 submission, hearing/argument on the 24th at 1:00 p.m.

14 MR. GEOPPINGER: Thank you, Your Honor.

15 MR. KASS: Thank you.

16 SPECIAL MASTER VANASKIE: Thank you.

17 Anything else on that?

18 LAW CLERK: Judge, this is Loretta.

19 SPECIAL MASTER VANASKIE: Yes.

20 LAW CLERK: May I ask the parties that are going to
21 appear -- Teams is a little bit different, so to lessen
22 Larry's load, may we ask the parties who plan to appear
23 that -- for that hearing on the fact sheets to email him or
24 let the Court know who he needs to invite.

25 MR. GEOPPINGER: Certainly.

1 LAW CLERK: Thank you.

2 SPECIAL MASTER VANASKIE: All right. Thanks,
3 Loretta.

4 THE COURT: All right. You also -- this is Judge
5 Kugler again.

6 You're talking some about supplemental depositions of
7 damages experts and you may ask Judge Vanaskie to decide
8 something if you can't come to an agreement.

9 Is that still correct?

10 MR. HONIK: Good afternoon, Your Honor, Ruben Honik.

11 That is correct. And regrettably, we haven't been
12 able to come to an agreement with the defendants and need to
13 place the matter before Judge Vanaskie.

14 THE COURT: Okay. Do you want to schedule for that?

15 MR. HONIK: My own view is that this is a rather
16 simple and straightforward matter. I will say that
17 Mr. Ostfeld for the defendants and I have made some progress,
18 modest as it may be. My view is that we could probably
19 discuss it in the course of the next five or ten minutes and
20 knock it out.

21 That's just my view.

22 THE COURT: Judge Vanaskie, do you want to tackle it
23 right now?

24 SPECIAL MASTER VANASKIE: Yeah, let's tackle it right
25 now, if it can be done.

1 Mr. Ostfeld, do you think we can do that?

2 MR. HONIK: You're muted, Greg.

3 MR. OSTFELD: Apologies, can everyone hear me?

4 SPECIAL MASTER VANASKIE: Yes.

5 MR. HONIK: Yes.

6 MR. OSTFELD: Yes. I think we can cover it today.

7 We came prepared to argue it today.

8 SPECIAL MASTER VANASKIE: Okay. Very well. Why

9 don't we just get right into it then.

10 Is that all right, Judge Kugler?

11 MR. HONIK: Yes, Judge, I'm happy to jump in and

12 perhaps provide a little bit of reminder context of what this

13 is all about.

14 So Dr. Conti, as I think everyone knows, is our

15 health economist expert. She's provided to this point four

16 different reports.

17 The first couple related to our motion for class

18 certification. The two more recent reports relate

19 specifically to third-party payor damages and even more

20 specifically MSP damages. She prepared a report that

21 calculated the damages, the relevant damages, as it concerns

22 our upcoming trial sometime in February of last year.

23 In that regard, she underwent a nearly seven-hour

24 deposition in July of this past year, producing 269 pages of

25 testimony, and having gone -- undergone extensive examination

1 about the basis for her opinions.

2 Let me just say that the calculations that she
3 articulated in her report then were no different than the two
4 previous reports supporting our cert motion, which is to say
5 an analysis that says the damages occur at the point of sale
6 and that the formula to apply to ascertain damages is knowing
7 the number of pills sold and their price.

8 And what she did at our request more recently,
9 specifically on December 1st of this past year, so just a
10 month ago, she prepared a very limited supplemental report
11 based upon a new dataset that we got from the retailers fairly
12 recently. In particular, we got claims data, that is, pricing
13 data, from Albertsons, CVS, Express Scripts, Humana, Kroger,
14 Optum, Rite Aid, Walgreens and Walmart.

15 And we thought it appropriate to ask her, applying
16 the identical methodology, the identical formula that she's
17 done on three prior occasions, to that new dataset so that the
18 fact-finder potentially has another snapshot of what the
19 damages are at the point of sale.

20 And so that's precisely what she did. She prepared a
21 very brief report. She talked about -- a little bit about
22 generic pricing at these large pharmacy chains, devoted maybe
23 two or three sentences to it. But essentially took the same
24 formula, that is to say, number of pills at the point of sale,
25 and this time took the average pricing from this sample of

1 nine retailers or pharmacies, and, you know, produced values
2 or numbers so that the jury can now look at alternative
3 modeling but using the same methodology.

4 With that backdrop, Judge, and in view of the fact
5 that Dr. Conti has been deposed three times, most recently for
6 almost seven hours on this very narrow subject of damages, we
7 had proposed that the defense confine her examination to a
8 more limited number of hours rather than the seven permitted
9 by the rule and to confine the questioning to the scope of her
10 supplemental report.

11 And needless to say, we wanted to do that
12 reciprocally with the defense expert who has now seen these
13 datasets, has seen the report, and has himself authored a
14 report. Whatever number of hours we would agree to, we would
15 agree, you know, mutually.

16 So we made some progress. I don't want to speak for
17 Mr. Ostfeld, but I think he conceded that it's highly unlikely
18 to require seven hours of examination, but the only progress
19 we made was a suggestion that we try -- emphasis on try -- try
20 to confine the examination to four hours but not relinquishing
21 the right to go the full seven, could become necessary, and,
22 frankly, not wanting to confine it to the supplemental report
23 on the theoretical basis that there were some elements of it
24 that are related to the earlier reports.

25 And so in effect, it was a kind of hoped-for proposal

1 to keep it to four. And we just thought that that was
2 unnecessary and inappropriate at this juncture.

3 What we would propose, Judge, in effect we're asking
4 for a ruling under 26 to limit the -- both time and scope.

5 We believe mutually that two hours is more than
6 sufficient time to examine Dr. Conti for the fourth time and
7 to confine it to the supplemental report, particularly
8 inasmuch as all she has done is taken the same methodology and
9 formula she's employed in each of her previous reports and
10 simply plug in new pricing from this sample dataset.

11 So with that, we would propose a limiting order to
12 two hours of examination, both for Mr. Gibson, the defense
13 expert, and Dr. Conti, our expert, and to confine the
14 questioning as closely as possible to the supplemental report
15 and only the supplemental report.

16 That's our position.

17 SPECIAL MASTER VANASKIE: All right. Thank you.

18 Mr. Ostfeld?

19 MR. OSTFELD: Thank you, Your Honor.

20 I respectfully disagree a little bit with Mr. Honik's
21 description of the report in terms of it being narrow and
22 limited. What we're talking about is a supplemental damages
23 report that asserts \$550 million in damages for the upcoming
24 TPP trial. That's based on not an analysis of one new
25 dataset, it's new pricing data derived from 169 separate

1 datasets from the nine pharmacy chains that Mr. Honik
2 mentioned as well as volume data from the IQVIA Xponent
3 dataset that purports to reflect almost a billion transactions
4 for 31 at-issue drugs in the TPP trial.

5 Notably, this is a pretty significant departure from
6 Dr. Conti's original damages report which calculated more than
7 \$1.3 billion in damages for the TPP trial using different
8 pricing data and the same volume data.

9 It's our understanding that plaintiffs plan to
10 present both sets of opinions at the TPP trial.

11 Additionally, and not mentioned, was that 17 days
12 after the supplemental report was due and disclosed,
13 plaintiffs further disclosed 12 megabytes of putative
14 supplemental tables and logic files that purport to provide
15 state-specific calculations for all 50 states, DC and Puerto
16 Rico, 43 of which are at issue in the TPP trial, and none of
17 these state-specific calculations were provided in connection
18 with the prior report.

19 Respectfully, that's just a lot to digest for a
20 high-stakes trial that's just ten weeks away. And what we're
21 seeking is a fair opportunity to question Dr. Conti about her
22 new opinions and how they relate to her old opinions.

23 I believe what plaintiffs proposed was two hours
24 strictly limited to the contents, the four corners of the
25 supplemental report.

1 Our counterproposal, we just sought two additional
2 hours, a total of four hours, which would be focused on the
3 supplemental report but with a fair opportunity to explore
4 other topics that we view as fair game outside the four
5 corners of the supplemental report.

6 And I'll address the proposed length restriction
7 first and then the topic restrictions.

8 So for length, of course, our starting point is the
9 seven hours that's provided under Rule 30(d)(1).

10 And when the defendants agreed with the plaintiffs
11 last month, the plaintiffs could provide a supplemental
12 damages report. And when we further agreed to a supplemental
13 deposition schedule which we disclosed to the Court on
14 December 15th, to that point plaintiffs had said nothing about
15 either time limits or subject matter limits for the
16 deposition. That was something that was raised four days
17 later, on December 19th.

18 And although we didn't think it was necessary to have
19 limits beyond those in Rule 30, we met and conferred, and then
20 we did propose to reduce our time from seven hours to four
21 hours, which we view as more than reasonable when you're
22 dealing with 170 data sources, \$550 million in damages, an
23 almost \$800 million discrepancy between two sets of damages
24 calculations that are going to be presented at trial, and 11
25 megabytes of late disclosed 50 state tables and logic files

1 with state-specific damages.

2 It's also I think relevant, Your Honor, though not
3 central, that Dr. Conti has historically been on the more
4 loquacious and detail-oriented side of witnesses. I don't
5 mean that in any way pejoratively. It's just the reality of
6 this witness. It's fair to say that she provides somewhat
7 lengthier answers than average and often seeks clarification
8 of questions.

9 And that's all fine. Witnesses aren't required to be
10 concise, and it's our job as the attorneys to adapt to the
11 witness's style. But when you have a witness that tends to be
12 a little bit more vocal, it does mean you need a little more
13 time to question her. And that was another concern about the
14 two-hour limit.

15 So that's why we seek four hours, Your Honor. We may
16 not need the full four hours, but we feel like as an outer
17 boundary, four hours is appropriate.

18 I also do want to correct, we weren't saying four
19 hours as kind of an aspirational goal, but we could take the
20 full seven hours.

21 I think what we proposed was if there was still a
22 topic being concluded when we got to four hours, that there
23 would be a fair opportunity to conclude the topic. And that's
24 just because in the past, when we've hit time limits, there's
25 been some dispute over whether the questioning must be cut off

1 at the exact moment where the time limit expires. We just
2 want to make sure if there's a topic ongoing, that we have a
3 fair opportunity to finish that topic.

4 Now, with respect to the subject matter, Your Honor,
5 we've made clear, we're not looking to have needless
6 repetition or to go through prior lines of questioning that
7 were covered in prior depositions. Nobody needs that.

8 The supplemental depositions will be properly focused
9 on the contents of the supplemental reports. Our only
10 opposition is to a strict confinement of the deposition to the
11 four corners of the report. We think, respectfully, that we
12 need a fair opportunity to ask about certain other topics that
13 we think are fair game. And I have a few illustrative
14 examples.

15 For one, Dr. Conti's new report in the first
16 paragraph incorporates by reference her three prior reports.
17 And she also expressly relies upon volume data from the IQVIA
18 Xponent dataset that she analyzed in more detail in her prior
19 damages report. We think we should be permitted to question
20 her regarding her reliance on prior reports and prior datasets
21 in the new report.

22 Second, Your Honor, Dr. Conti's 50 state tables that
23 we got 17 days after her supplemental report aren't within the
24 four corners of the report, but, respectfully, if they're
25 going to be presented at trial, we need a fair opportunity to

1 question her about the 50 state calculations. That's
2 something that hasn't been previously disclosed and was not
3 part of her prior damages report. This would be our first
4 opportunity to question her on state-specific calculations.

5 And third, because plaintiffs have advised, at least
6 we understand that Dr. Conti's new report is an alternative
7 calculation to her original, we think we need a fair
8 opportunity to question her regarding the relationship between
9 the two reports, the comparison of the two reports, and how
10 the new report impacts her opinions in the old report.

11 When you're dealing with an \$800 million -- almost
12 \$800 million delta in damages, that raises a lot of questions
13 about how these two reports interact with one another.

14 So respectfully, Your Honor, we think these topics
15 are all properly raised, even though they're outside the
16 precise four corners of the supplemental report, and we don't
17 think there should be an artificial or arbitrary exclusion of
18 topics like this, given Dr. Conti's reliance on prior
19 materials and the interaction between the old opinions and the
20 new opinions.

21 So we're not looking to repeat questioning, but we
22 do -- we don't want to be prevented from asking about these
23 topics or appropriate follow-up questions to any testimony
24 that Dr. Conti provides when she's explaining and describing
25 her supplemental opinions.

1 Another option, of course, Your Honor, is if you're
2 available, you're also welcome to attend these depositions and
3 preside over them. And that may shorten the questioning, and
4 it may also enable us to resolve disputes as they come up,
5 which, you know, could maybe enable us to do this more
6 efficiently.

7 We have no objection to that if Your Honor is
8 available. We also aren't -- don't think it's necessary.
9 We've always been able to work out these issues in the past.
10 But if Your Honor wishes to attend, you're certainly welcome
11 to attend these depositions.

12 With that, I think that's defendants' position, and
13 we would welcome your ruling.

14 SPECIAL MASTER VANASKIE: Go ahead, Mr. Honik.

15 MR. HONIK: Your Honor, you know, it's amusing to
16 me -- and I'm very fond of Greg, but you talk about
17 loquacious. There's no better example of why we want to limit
18 this to something substantially less than seven.

19 Look, at any point in a case of this magnitude, one
20 can look at the number of pills sold and the data that
21 captures it and say, oh, my god, it's so enormous, the roof is
22 falling in.

23 I have now attended three of her depositions, each of
24 which lasted seven hours, and not once did anybody dive in at
25 the depth that Mr. Ostfeld suggests may occur here to the

1 dataset. Nobody is looking at the billions of captured pill
2 amounts at all.

3 And let me just say that their own expert was able to
4 digest everything that he just described in a couple of weeks
5 and turned around a very succinct report, who basically says
6 the data is the data. And all that Dr. Conti did was to input
7 this new pricing.

8 The only -- literally the only difference in the
9 reports is that from these nine retailers, we have some
10 pricing. And it's not the entire universe of pricing, which
11 is what IQVIA captures, it's a subset.

12 So I don't -- I don't foreclose the idea that yes,
13 there is some interrelationship between her prior opinions and
14 the ones reflected here. And Mr. Ostfeld should have an
15 opportunity to explore them within the confines of these new
16 values. And I think two hours is ample to do that.

17 And, Judge, you've been down this road a million
18 times. They think it's four hours, we think it's two, so, you
19 know, somewhere between our perception of what it is and their
20 perception is probably where this thing should fall. That's
21 number one.

22 Number two, I think it's semantically incorrect to
23 say that we want some strict adherence to the issues within
24 the four corners of the Complaint. We've all been doing this
25 long enough to know that there is relatedness to some of her

1 other opinions. And I'm confident that we can manage
2 ourselves within the confines of that pathway once we go to
3 examine her. And I don't want an order that says it shall be
4 strictly confined to the issues. I think an order that says
5 it shall be reasonably confined to the issues raised in the
6 supplemental report is adequate. And I think we can police
7 ourselves.

8 But I think the key thing is to bring this under some
9 reasonable control and not have another seven-hour deposition
10 and, frankly, not have another four-hour deposition. We can
11 do Dr. -- Mr. Gibson in two hours, they can absolutely do
12 Dr. Conti in two.

13 And I'll say this as well. If we're nearing the
14 clock on two hours and Greg says to me, Ruben, I've got
15 another 15 or 20 minutes because she's loquacious, you can
16 rest assured that we'll give him the 15 or 20 minutes.

17 But parties need restraints. Fences and borders are
18 good things to have in litigation like this. And I would urge
19 Your Honor to limit us to a reasonable amount of time knowing
20 that reasonable lawyers can expand a little bit as needed in
21 real time.

22 Two hours is the right number.

23 SPECIAL MASTER VANASKIE: All right. I always hated
24 resolving things of this nature.

25 I'm going to -- and we'll issue an order -- grant

1 Mr. Ostfeld's request that he have four hours of deposition to
2 conclude. I hope he doesn't have to use four hours, but --
3 you're both exceptional lawyers, and you make reasonable
4 estimates of the amount of time you're going to require.

5 I was pleased Mr. Ostfeld didn't argue for seven
6 hours. And four hours, I hope it doesn't require four hours,
7 but we'll give him those four hours.

8 And I expect, Mr. Honik, that when you get to those
9 four hours and if he has another 10, 15 minutes, you'll be
10 accommodating, as long as he's reasonable. And let's proceed
11 on that basis.

12 In terms of my sitting in on the deposition, I've
13 done that before. I'm not a fan. I don't think it's
14 necessary. I think, especially with lawyers of your quality
15 and experience, that it is unnecessary. If you both agree
16 otherwise, and tell me the date, I'll see if I'm available;
17 but otherwise, I don't intend to sit through a deposition and
18 rule on objections. All right?

19 Any questions?

20 MR. HONIK: No, Your Honor. Thank you.

21 MR. OSTFELD: No questions, Your Honor. Thank you.

22 SPECIAL MASTER VANASKIE: All right. We'll issue an
23 order that limits the resumed deposition to four hours.

24 And in terms of its topics, we won't say anything
25 other than they have to be reasonably related to the

1 supplemental report.

2 I understand there will be a need to go back and
3 forth in terms of questioning how this supplemental report
4 relates to the original report. All right?

5 MR. OSTFELD: Your Honor, the only request I would
6 make on that is if it could also encompass the 50 state tables
7 that were received after the supplemental report.

8 THE COURT: It can include the 50 state tables issued
9 after the supplemental report. And we'll make that clear as
10 well. All right?

11 MR. HONIK: Thank you, Judge.

12 SPECIAL MASTER VANASKIE: Anything else?

13 MR. HONIK: Not on this.

14 MR. OSTFELD: No, Your Honor.

15 SPECIAL MASTER VANASKIE: Okay.

16 THE COURT: This is Judge Kugler again.

17 We still have -- you raised the issues of the
18 pretrial order, in limine motions and the jury questionnaire.

19 Let's start with the jury questionnaire.

20 Are there any disputes as to what's going into this
21 jury questionnaire?

22 MS. LOCKARD: Your Honor, it's Victoria Lockard for
23 the defendants.

24 We have been working on a proposed jury questionnaire
25 that we have indicated we would turn over to plaintiffs for

1 their review and comment.

2 And we have -- Mr. Ostfeld has put together a
3 proposed schedule that incorporates many of the timelines and
4 internal deadlines that we were contemplating. But my
5 estimation is that we should be able to get that questionnaire
6 draft over to plaintiffs within about ten days to two weeks,
7 get their input, and then be able to submit that to you
8 sometime before February or in early February.

9 THE COURT: Well, if there's an agreement on it, I
10 really don't need it till just before trial. But if
11 there's -- obviously, if there's some disputes, then I'll need
12 it before that so we can resolve the disputes. Okay?

13 The pretrial order, what questions do you have about
14 the pretrial order?

15 We have a form of order that we use in New Jersey.
16 It essentially involves the plaintiff going first, completing
17 its portion of the pretrial order; submitting it to defense
18 counsel, who then complete their portion of it, send it back
19 to plaintiffs' counsel; then everybody signs and files it.

20 We expect you to spend a lot of time on the pretrial
21 order. It's very difficult to introduce any evidence in the
22 trial if it's not in the pretrial order. Let's leave it at
23 that.

24 And we expect -- there will be a section where you
25 can list your witnesses that you contemplate might testify at

1 trial. And you also have to list what you think they're going
2 to testify to. You will need to spend some time on that,
3 because to say that they're going to testify as to the facts
4 and circumstances of the case is not going to make it.

5 But anyway, again, I don't expect there should be any
6 disputes about what goes in it, because you pretty much have
7 carte blanche on both sides as to what you want to put in this
8 thing.

9 But obviously we need to get that filed before we
10 start the trial, so what are your proposals about that?

11 MR. OSTFELD: Thank you, Your Honor. This is Greg
12 Ostfeld.

13 And we've -- obviously, we've spent a lot of time
14 looking at the Court's form final pretrial order for the
15 Camden division. And we've been regularly meeting and
16 conferring with plaintiffs. And we've sent them a fairly
17 detailed proposal for the back and forth exchange of the
18 various components of the final pretrial order.

19 I think the most important question we all have is
20 when Your Honor wants the final pretrial order. The form
21 doesn't necessarily have a specific deadline for that. It
22 covers a few elements of it, like the trial briefs and the
23 jury questions seven days before trial.

24 We wanted to know if that seven-day deadline applies
25 to the full final pretrial order or if you want pieces of it

1 or portions of it more than seven days before trial?

2 THE COURT: Well, first of all, don't worry about the
3 voir dire questions, because that's going to be covered in
4 your jury questionnaire.

5 Anyway, seven days before trial is fine, completed
6 and signed by all the attorneys who are going to be appearing
7 in the case. Okay?

8 MR. OSTFELD: All right. Thank you, Your Honor.

9 THE COURT: Now, in limine motions, what are we doing
10 about that?

11 MR. OSTFELD: Your Honor, as part of our proposal to
12 plaintiffs' counsel, we also included a proposed schedule on
13 the in limine motions.

14 I just got this to them essentially a few days before
15 the holidays. I don't think they've had an opportunity to
16 digest it and respond yet, so it may be that setting a
17 schedule on in limine motions would be premature until we've
18 had a chance to meet and confer on that issue.

19 If Your Honor has a sense of when you'd like the in
20 limine motions, that would certainly provide us with some
21 guidance; but otherwise, we can meet and confer on that issue
22 and make a recommendation to the Court.

23 THE COURT: Well, it depends entirely on what the
24 motions are as to when I want to see it.

25 I mean, based on the practice so far, I expect

1 thousands of pages. That's not something we can turn around
2 in a week.

3 All kidding aside, please don't make the mistake of
4 disguising dispositive motions as in limine motions, because
5 I'll just deny them out of hand. I see that all too often
6 with lawyers, and I don't expect to see it from you.

7 But again, I have no idea what in limine motions
8 you're contemplating, so I don't know how much time I'll need
9 to go through them.

10 But perhaps when we speak next month, we can have a
11 better idea about this. Okay?

12 MR. OSTFELD: That seems fair, Your Honor.

13 THE COURT: Anybody else want to be heard on these
14 issues, about the in limine motions, the pretrial order,
15 things of that nature?

16 MR. SLATER: I don't think so for plaintiffs, Your
17 Honor. I think your guidance helps us to reengage with the
18 defendants.

19 THE COURT: Anything else you want to talk about
20 today?

21 I promise I will get this Teams thing mastered before
22 the next hearing.

23 I don't know. This worked great for Zoom. But for
24 some reason, the federal government, despite spending \$6
25 trillion a year, can't find the money to fund Zoom accounts

1 anymore. I don't get it, but I don't make those decisions.

2 This is my editorial for the day.

3 Anything else you want to talk about?

4 SPECIAL MASTER VANASKIE: I think -- I think I'm
5 going to hear argument on the motion to seal exhibits filed in
6 connection with the class certification motion if counsel is
7 prepared to discuss that today.

8 But, Judge Kugler, that's the only thing I have.

9 THE COURT: Well, why don't we schedule the next
10 meeting.

11 How about February 1st? Can we do that? It's a
12 Thursday --

13 MR. SLATER: Yes.

14 THE COURT: -- four weeks from today.

15 1:00?

16 MR. SLATER: That sounds good, Judge.

17 THE COURT: All right. We'll do it again at 1:00.

18 And, Judge Vanaskie, do you want to hear argument?

19 SPECIAL MASTER VANASKIE: Yes, on the motion to seal
20 exhibits that were filed in connection with one of the class
21 certification motions. It's been pending for some time now,
22 but I think we can resolve it.

23 And I guess I'd ask who would be presenting argument
24 for the defense, since it's their request, and who will be
25 presenting argument for the plaintiffs.

1 MR. HARKINS: This is Steve Harkins with Greenberg
2 Traurig. I'll be presenting for the Teva defendants.

3 MS. HILTON: And Your Honor, this is Layne Hilton,
4 and I'll be presenting for the plaintiffs.

5 SPECIAL MASTER VANASKIE: Very well. All right.

6 Mr. Harkins, I think you have a tough road to hoe
7 here with respect to sealing these exhibits in lieu of the
8 fact that they were presented in connection with an
9 adjudicatory proceeding.

10 There is a presumption of public access, and you have
11 to show clearly defined and serious injury if the information
12 is disclosed.

13 And I've read each of -- there's only six documents
14 at issue. I've read each of the six documents. And I'm
15 really struggling with how Teva would be harmed by having
16 these documents in the public domain.

17 So having said that, I'll turn it you.

18 MR. HARKINS: Your Honor, in deciding to continue to
19 maintain confidentiality and seeking to seal these six
20 documents, we looked at your prior order in Special Master
21 Order Number 47 that evaluated the confidentiality of certain
22 documents. And that order did note that because those
23 documents had not yet been submitted as part of the public
24 record, that presumption did not apply.

25 It has been a long time since we went through this

1 exercise with plaintiffs.

2 SPECIAL MASTER VANASKIE: It has.

3 MR. HARKINS: But as correctly referenced in
4 plaintiffs' brief, the initial body of documents that were
5 potentially going to be subject to the motion to seal was
6 very, very large. And we were able to identify both from your
7 guidance in prior orders on confidentiality and keeping in
8 mind the presumption that you referenced of public access in
9 narrowing it down to just these six documents.

10 And I am happy to go through them one by one, if the
11 Court thinks that would be necessary or helpful, but at a high
12 level, the basis for seeking to seal these particular
13 documents we believe is set forth in the affidavit presented
14 by Mr. Binsol as well as the content of the documents
15 themselves.

16 Each of these documents provides a roadmap to Teva's
17 internal processes, which, while they are not formulations,
18 are formula that Teva considers proprietary. It explains how
19 they handle a certain number of very poor functions with
20 regard to specifically their API suppliers, API suppliers who
21 are either negotiating directly in business with Teva or are
22 competing with Teva as API suppliers to other companies.

23 In all of the instances of these documents, there is
24 information that an API supplier, either negotiating directly
25 with Teva or working with one of Teva's competitors, could use

1 to determine Teva's internal policies, evaluate how those
2 policies are implemented specifically by Teva, in material
3 that is not shared publicly.

4 To the extent these types of documents are ever
5 communicated outside of the company, they are held as strictly
6 confidential and communicated only to the parties who are also
7 involved in that relationship.

8 As set forth in Mr. Binsol's declaration submitted
9 here, we have a description of each of the documents. And I
10 think it goes without saying that these are not ordinarily
11 disclosed to the public.

12 He describes the particular policies and procedures
13 that are at issue, some in more detailed reports and some in
14 the extensive email communications that surround production of
15 those reports. And the competitive harm, though slightly
16 different in each instance here, is it enables Teva's API
17 suppliers to have proprietary information that would enable
18 them to competitively disadvantage Teva either in direct
19 negotiations or, as said, in negotiations with other API
20 suppliers.

21 I'm happy to go into more granular detail on that,
22 but on that basis --

23 SPECIAL MASTER VANASKIE: I think you're going to
24 have to go into --

25 MR. HARKINS: Sorry.

1 SPECIAL MASTER VANASKIE: I think you're going to
2 have to go into more granular detail, because I'm looking --
3 you know, what you say in a broad sense, that would deserve
4 protection. But when I read the documents themselves, I'm not
5 seeing that.

6 MR. HARKINS: Sure. So, Your Honor, if you'd like to
7 take a look, and I'm happy to go by a specific document, for
8 example, the one ending in Bates 49024.

9 SPECIAL MASTER VANASKIE: What exhibit number is
10 that? I have them by exhibit number.

11 MR. HARKINS: That is Exhibit Number -- apologies.
12 My cover sheet doesn't have it.

13 That is Exhibit Number 16 and 17 to Defense
14 Exhibit --

15 SPECIAL MASTER VANASKIE: 16 and 67?

16 MR. HARKINS: 16 and 67, yes.

17 SPECIAL MASTER VANASKIE: Yes. I have that in front
18 of me.

19 MR. HARKINS: So, Your Honor, what this represents is
20 an investigation report. And the investigation report
21 specifically here is looking into the nitrosamine issue.

22 But what this report demonstrates is not just a
23 single Teva policy but a number of Teva internal policies and
24 how those policies are implemented when performing this type
25 of investigation.

1 So it goes beyond simply disclosing a Teva policy or
2 a policy that might be mandated by CGMPs and illustrates for
3 any one of Teva's competitors how these sensitive internal
4 investigations, which are not ordinarily shared outside the
5 company at all, are conducted.

6 SPECIAL MASTER VANASKIE: Well, what -- can you point
7 to specific language that shows that? As I said, I've read
8 the exhibit, and I'm having trouble finding that.

9 MR. HARKINS: So, for example, Your Honor, on the
10 second page under heading number 2, this lays out Teva's
11 internal policy of issuing a global notification to
12 management. It provides a timeline of when Teva sent
13 notifications to regulatory authorities. It describes Teva's
14 performance of a toxicological assessment. It describes
15 additional testing that Teva performed. And it describes what
16 they did as a result of the testing that was performed.

17 And while individually all of these may seem like
18 simple responses to CGMP requirements or something that might
19 be ordinarily done, the entire content of the document is to
20 provide a roadmap that anyone looking at it would have a very
21 clear understanding of Teva's processes and procedures for
22 performing this type of investigation.

23 MS. HILTON: Your Honor, if I may.

24 THE COURT: Go ahead, Ms. Hilton.

25 MS. HILTON: I would have to say that I -- that the

1 document references specific policy numbers is immaterial to
2 the fact that everything that Teva was doing in this
3 document -- which, by the way, was authored, you know, more
4 than six years ago -- was something that was rooted from their
5 obligations under good manufacturing practices. And those
6 obligations under good manufacturing practices are an
7 industrywide roadmap.

8 So to the extent -- you know, I would understand if
9 this document referenced particular suppliers that weren't
10 just otherwise disclosed or particular routes of syntheses in
11 these -- you know, the manufacturing of their drugs that
12 wasn't disclosed. But I don't think anyone in the industry
13 reading this wouldn't -- wouldn't agree that this was how or
14 that these were the sorts of activities that might be
15 undertaken. I don't think there's anything proprietary or
16 confidential about it.

17 And I think that as we set forth in our brief, the
18 fact that Teva's own employees issued public press releases,
19 they did industrywide talks about how they handled this
20 particular crisis that, again, was now as we're looking back
21 more than six years ago, would demonstrate that this isn't
22 information that they keep within themselves, this is
23 information that is across the industry and well known.

24 SPECIAL MASTER VANASKIE: Mr. Harkins, I'm looking at
25 the document.

1 So under heading number 2 or paragraph 2, Teva's
2 immediate actions on 6 November 2018, a global notification to
3 management issued, all products containing Mylan valsartan API
4 were placed on temporary hold.

5 What's confidential about that?

6 MR. HARKINS: The individual facts that are
7 referenced in this document are, as, you know, admittedly
8 plaintiffs point out mostly either a matter of public record
9 or something that has been communicated outside and externally
10 by Teva whether to the public at large or to regulators.

11 We are not seeking to keep these documents under seal
12 because they contain a reference to an individual action that
13 Teva took at one time. And the public interest in having
14 access to that information is not curtailed by keeping this
15 material under seal. Those documents are -- I'm sorry, those
16 facts are, generally speaking, already a matter of public
17 record.

18 What this document does is it provides detailed
19 analysis internal to Teva about how they evaluate and
20 implement their own processes in response to these facts. The
21 information here is really only applicable or interesting to
22 someone like an API supplier who might want to know how Teva
23 is going to evaluate issues that arise in the course of their
24 business relationship, how they're going to conduct
25 investigations.

1 This material when compiled in this fashion as an
2 internal report is different than the type of external
3 reporting and presentations that Teva makes to the public and
4 to regulators.

5 The map here is the problem. It's the confluence of
6 all of these facts in a very particular way that provides a
7 competitor insight into Teva's practices in a way that is
8 really only useful to a competitor and not the public.

9 MS. HILTON: I mean, respectfully, Your Honor, I
10 simply would disagree. I don't think that this document
11 provides a roadmap at all, and I think the fact that Teva
12 would concede that the underlying facts in this document are
13 public is probably fatal to their argument that they should
14 somehow overcome the presumption of public access here for
15 these court documents.

16 MR. HARKINS: And, Your Honor, just to clarify, I'm
17 not conceding that all of the facts contained in this document
18 are a matter of public record, but, for example, the fact that
19 Mylan valsartan API were placed on a temporary hold in and of
20 itself is not the type of document that we are seeking to
21 seal. And there are any number --

22 (Technological interruption.)

23 MR. HARKINS: Apologies.

24 And there are any number of documents that reflect
25 individual facts like that, that in determining what material

1 we were going to move and seek to keep under seal, we
2 excluded, where it contains an isolated fact, something that
3 is either a matter of public record or not by itself
4 competitively sensitive information.

5 It is when all this information is compiled to
6 demonstrate how Teva's internal processes and thought-making
7 and decisionmaking play out that it becomes something that we
8 feel is competitively sensitive, sufficient to overcome the
9 burden of public access.

10 SPECIAL MASTER VANASKIE: Let me move to another
11 document.

12 MR. HARKINS: The next document, Your Honor, and I
13 believe this is the global quality report that was referenced,
14 actually, in a prior exhibit. And it is --

15 SPECIAL MASTER VANASKIE: Exhibit 66.

16 MR. HARKINS: Yes.

17 And this report contains similar information and I
18 think is appropriately categorized in a similar way.

19 This reflects any number of Teva policies that are
20 specifically being implemented here in their evaluation of a
21 supplier, commentary on that supplier. And again, while the
22 individual facts referenced may in any number of instances be
23 elsewhere a matter of public record, it will be something that
24 Teva has provided to a regulator or to the public at large.

25 When the information is compiled in this way, it

1 provides a roadmap into how Teva conducts its own internal
2 policies, investigations and evaluations of its suppliers.
3 That information, again, would very likely only be relevant or
4 useful to an API supplier either seeking to contract directly
5 with Teva or working with one of Teva's competitors.

6 MS. HILTON: Your Honor --

7 THE COURT: So -- go ahead, Ms. Hilton.

8 MS. HILTON: I would just point out, I think that
9 this document that Mr. Harkins references, this is another one
10 where, you know, I can't recall, this was so long ago, I
11 believe I may have even agreed to redact out some of the names
12 of the people and the entities from whom Teva supplies
13 valsartan API except for from Mylan. But aside from that,
14 there is nothing in here that isn't otherwise referenced in
15 the public.

16 And I don't -- this idea that -- you know, that any
17 such report could lay -- set forth a roadmap, I mean, I think
18 that's such an amorphous harm, it's not the sort of clear and
19 concrete harm that Avandia requires.

20 And so it's almost difficult to argue about why this
21 isn't or shouldn't be sealed, because it's -- there's so much
22 in here that's in the public that it's almost anathema to
23 argue it.

24 So I think that the argument that these documents
25 provide some sort of roadmap, I don't believe that that really

1 meets the harm requirement that Avandia requires.

2 SPECIAL MASTER VANASKIE: Any reply, Mr. Harkins?

3 MR. HARKINS: Your Honor, again, without taking each
4 of these specific facts separately, some of these may be in
5 the public record elsewhere. To the extent they are, the
6 interest in the public of having that information available
7 from these specific documents is minimal to nonexistent.

8 What these documents do, the same way that having
9 Teva produce its own corporate policies in the public record,
10 is provides competitors with the ability to copy into it based
11 on how those policies are implemented to strategize against
12 Teva. That's what's set forth in Mr. Binsol's declaration.

13 This is material that Teva internally views as
14 competitively sensitive and proprietary in the same way that
15 the formulation information for their drugs is viewed as
16 competitively sensitive and proprietary.

17 And we think that providing this type of information
18 in this format -- and we are not saying that every document
19 that references any of these individual facts that may be in
20 the public record needs to be sealed, which is why we've
21 selected this very narrow subset of material to try and
22 maintain under seal rather than keep all of the attendant
23 facts separate.

24 And just one other point to the idea of redacting out
25 individual names here. That sort of gets the entire issue

1 from a proprietary and competitive standpoint backwards.

2 The problem with allowing these documents into the
3 public record is not that it states that ZHP did something on
4 a certain date. The problem is that it provides insight for
5 anyone else competing with Teva into how Teva is going to in
6 the future implement its own policies and try and evaluate a
7 supplier in any sort of similar situation where these types of
8 investigations are being undertaken or where similar internal
9 policies are being implemented.

10 That's the basis, again, for our seeking -- and I
11 apologize for the frog in my throat -- seeking to seal this
12 narrow set of documents and specifically these first two
13 reports.

14 SPECIAL MASTER VANASKIE: Let me read from the
15 conclusion on page 3 of this Exhibit 66, the global quality
16 report, and then ask you, Mr. Harkins, how that disclosure of
17 that information would provide this roadmap to Teva's
18 competitors or those who want to deal with Teva, you know, API
19 providers.

20 So the conclusion says: Based on the executed Teva
21 toxicology assessment and the health hazard assessment, Teva
22 will continue to develop product quality data before it
23 executes a worldwide recall of all valsartan single and
24 combination products containing API manufactured by Zhejiang
25 Huahai Pharmaceutical Company Limited. In the meantime, any

1 authority request recall initiated will extend to pharmacy
2 level unless otherwise instructed by a regulatory authority.
3 All other valsartan finished products using the API from
4 alternate manufacturers shall remain on the market unless
5 further notification is received to recall. The temporary and
6 precautionary hold status placed on all API and finished
7 products manufactured using non-ZHP material shall be lifted.

8 How does that provide a roadmap to how Teva does
9 business?

10 MR. HARKINS: Your Honor, the way that that would
11 allow someone to understand Teva's processes is to look back
12 at the rest of the document which shows how Teva arrived at
13 that conclusion. And if someone was in a relationship with
14 Teva where they had to report this type of issue, this
15 document would demonstrate what type of internal assessment of
16 the supplier Teva would perform, what type of Teva
17 toxicological assessment would be performed, how Teva would
18 undertake a clinical safety assessment and arrive at that
19 conclusion, how they would perform their quality assessment,
20 and to the extent there are any steps that were not taken by
21 Teva, the supplier would also be aware that other analyses
22 which a different company might perform or request are, in
23 general, at least according to this roadmap, not going to be
24 undertaken by Teva in the course of investigating this type of
25 impurity.

1 So someone who is faced with a similar issue of
2 having to report something or having to raise an issue about
3 an impurity with Teva would have, from this document, a
4 step-by-step guide to the type of material that Teva is
5 looking to prepare to arrive at that conclusion that you
6 referenced on page 3.

7 MS. HILTON: Your Honor, if I may?

8 SPECIAL MASTER VANASKIE: You may.

9 MS. HILTON: If it is Teva's position that the
10 competitive harm that would befall them if these documents
11 came out is that a supplier or another pharmaceutical company
12 might not do business with them because they believe Teva does
13 not meet its obligations under CGMP or shortcuts its
14 investigations, then Mr. Binsol should have said that in the
15 declaration. He should have said the harm will be that
16 companies will not do business with us if they know how
17 lackadaisical our CGMP practices are. But instead, we have
18 these sort of broad and sweeping conclusions that don't really
19 identify or articulate that harm.

20 And furthermore, the paragraph that you read, and
21 what Teva did in the wake of the NDMA, you know, valsartan
22 recall is what every defendant in this litigation did. This
23 is -- you know, other documents that are very similar to this
24 in nature from the other manufacturers, they did not contest
25 that those documents should remain under seal. It is only

1 Teva --

2 You know, I tried to be very, very -- I tried to take
3 a very, you know, nice edge with this and tried to make sure
4 that we weren't bringing documents to you that -- you know,
5 that were on the margins. And other defendants did concede
6 that these sorts of investigation documents precisely such as
7 this one from Teva was -- you know, didn't contain the sort of
8 proprietary trade secret or information that would require
9 continued sealing of a public record.

10 SPECIAL MASTER VANASKIE: Thank you.

11 MR. HARKINS: Your Honor --

12 SPECIAL MASTER VANASKIE: Mr. Harkins?

13 MR. HARKINS: Apologies.

14 Just to make one point, the steps outlined in this
15 report and in the prior investigation do not simply meet some
16 minimum requirement as mandated by CGMPs. These are
17 implementations of Teva's internal policies, many of which,
18 including policies and steps undertaken and referenced in both
19 of these documents, go above and beyond normal minimum CGMP
20 requirements. This does not simply reflect the baseline
21 investigation or steps that any manufacturer was required to
22 undertake.

23 We believe that this material is proprietary. It is
24 sensitive to Teva. We believe that there is a proprietary
25 interest in maintaining its confidentiality, as Your Honor

1 agreed in connection with our initial ruling that was not,
2 admittedly, in connection with material being presented on the
3 public record.

4 Based on what we have presented in the affidavit of
5 Mr. Binsol, argument today and discussion of the individual
6 documents themselves, we feel that this proprietary internal
7 information is still sensitive enough and the competitive harm
8 to Teva specifically in allowing API suppliers to understand
9 how Teva is going to implement their own internal policies is
10 sufficient to overcome the presumption of public access.

11 We acknowledge that burden is different here.

12 And I'm happy to discuss the other documents more
13 broadly, though I think that the first two probably fall
14 pretty neatly into their own category as sort of the full
15 reports.

16 SPECIAL MASTER VANASKIE: The other documents are
17 email exchanges, as I recollect. And so, again, I'm having --
18 I really am.

19 What you say, Mr. Harkins, if the documents indicated
20 what you say, yeah, they'd be protected, but I'm not sure the
21 documents do that.

22 MR. HARKINS: Your Honor, with respect --

23 SPECIAL MASTER VANASKIE: That's my problem.

24 MR. HARKINS: My apologies.

25 And I understand Your Honor's comments. And with

1 respect to the emails, these do not provide as detailed of a
2 roadmap. And I believe the reason that we feel and submitted
3 the affidavit in support of their competitively sensitive
4 nature is that even more so than the reports, there are
5 internal discussions, thought processes among high-level
6 employees at Teva evaluating sort of two categories, two
7 emails that relate to the preparation of toxicological
8 assessments and then two emails related to Teva's internal
9 audit procedures.

10 Both of these documents -- or I'm sorry, both of
11 these categories of documents also contain analysis and
12 criticisms of Teva's suppliers, that demonstrates Teva's own
13 internal evaluation, again, of those relationships.

14 It is not as detailed a roadmap, but the specific
15 material discussed in there we do feel is still competitively
16 sensitive. It reveals Teva's own internal thought processes.
17 It reveals the way in which Teva implements their internal
18 policies in certain situations that would be relevant and
19 potentially competitively sensitive if they were disclosed to
20 broader the industry but more specifically API suppliers who
21 are negotiating with Teva.

22 MS. HILTON: Your Honor, if I may, just to sort of
23 center us in these documents, you know, with respect to Teva's
24 oversight of their API suppliers, that is at the core of this
25 case. That is -- that is not an ancillary issue here. That

1 is not a fringe issue. How Teva oversees its API suppliers is
2 the fundamental basis for this case and why Teva is in this
3 litigation to begin with.

4 And so keeping that in mind, when you understand that
5 that is the crux of this case and then reading these
6 documents, it's really almost incomprehensible to understand
7 what about this document, what about these email exchanges is
8 in any way the sort of material that would overcome the
9 presumption of public access.

10 SPECIAL MASTER VANASKIE: All right. Anything else,
11 Mr. Harkins?

12 MR. HARKINS: Your Honor, and I'm happy to talk in
13 more detail about the specific items, but just to say, our
14 client clearly views this material as confidential,
15 proprietary and sensitive. We understand the standard that
16 we're arguing against, and we've tried to be as narrow as
17 possible in submitting only these documents that we think
18 reflect things which are directly reflective of Teva's
19 internal policies and decisionmaking. But we understand the
20 Court's comments, particularly on the email exchanges as well.

21 THE COURT: Thank you for that.

22 I mean, I -- you know, I think it's commendable what
23 you did in terms of narrowing the dispute to six documents,
24 but I still have to analyze each document in the context of
25 Avandia. And that's what I'm struggling with.

1 I'll refer to Exhibit 72 and the specific page -- the
2 Bates number ends in 523, an email to Cory Sawyer and Edward
3 Coller (ph), death from -- I apologize for my pronunciation
4 problems -- Siauliai. And hi, Cory, thanks for the
5 information. The API manufacturer provided toxicology data
6 review and their calculation of potential exposure of NDMA. I
7 will forward this information to our nonclinical tox for their
8 review and agreement on the conclusion. It is difficult to
9 assess the potential risks of carcinogenic impurity using
10 postmarketing spontaneous reports.

11 The conclusion will be likely based on nonclinical
12 tox assessment on the exposure. However, I will conduct a
13 search in our postmarketing safety database and safety signal
14 detection system. Since the product has been distributed to
15 many countries, I will search all cases except US. I do not
16 see US in the distribution list.

17 Please provide me the earliest market release date
18 that will start the date for data burst -- I'm sorry, for
19 database search.

20 And finally, I will try to find any epidemiology
21 studies in public domain on the effects of NDMA.

22 Now, how does that cause irreparable -- not
23 irreparable but serious competitive harm to Teva?

24 MR. HARKINS: That specific email essentially lays
25 out Teva's internal process for following their policy of

1 performing this type of toxicology review. It's more general
2 than if the policy itself were attached and distributed for
3 Teva's competitors to review, but that three lines of
4 information provides a very general roadmap to exactly what
5 Teva is going to do in performing this toxicology assessment,
6 what databases they are going to search, the steps that they
7 are going to take and in what order. And in combination with
8 the rest of the email chain, which provides similar back and
9 forth describing target dates, internal dates that Teva has
10 set for performing certain actions, it gives a reasonably
11 accurate picture of not only how Teva chose to handle this
12 particular situation but how Teva would handle another
13 situation or performing a toxicology assessment.

14 And in the same way that we would view the internal
15 policy that reflects how those assessments are performed as
16 proprietary and confidential, we would view this email that
17 provides a high-level discussion and information walking
18 through the steps of how that is performed, we view that as
19 similarly proprietary.

20 SPECIAL MASTER VANASKIE: Now, plaintiffs have
21 presented evidence that Teva presented webinars dealing with
22 how it responded to the alleged contamination.

23 How does that differ from this information that's
24 been provided in these emails?

25 MR. HARKINS: Your Honor, the information that's

1 provided in these emails represents Teva's internal policies
2 which are certainly more detailed than the public-facing
3 descriptions and sort of general information that has been
4 provided to the public, particularly in the material that
5 plaintiffs cite to.

6 The general information that Teva shared with the
7 public about their response is not what is contained in these
8 documents. It's not what we are seeking to keep under seal.
9 We are seeking to keep under seal Teva's internal
10 communications that reflect their own analysis, discussion,
11 and steps in that process which are not a matter of public
12 record.

13 The fact of when Teva initiated a recall, the fact of
14 when Teva identified the presence of an impurity, that is not
15 the type of information that we are seeking to keep under
16 seal. It is the internal policies that lead to that decision
17 and the internal discussion that reflects how those policies
18 are implemented.

19 THE COURT: Ms. Hilton, anything else?

20 MS. HILTON: Your Honor, I would simply state that I
21 disagree that what we actually see within the four corners of
22 the documents is as clear a roadmap about policies and
23 processes and procedures as Mr. Harkins and Mr. Binsol state.

24 And just to your point, this -- you know, this
25 paragraph about the toxicological review, it seems to me that

1 this process is the same sort of process as baking a cake.
2 There are certain steps you of course take first, second,
3 third and fourth.

4 We sort of can't extend -- I think that because the
5 idea -- you know, because *Avandia* requires such a concrete
6 harm, I would simply argue that any sort of, you know -- the
7 idea that a roadmap is somehow sufficient to meet that
8 concrete harm that *Avandia* requires, I just don't think it
9 passes muster, quite frankly, because it's really quite
10 amorphous and it's almost difficult to argue against, because
11 taken at large, any -- any document, any document that a
12 company prepares in the course of its ordinary course of
13 business could potentially provide such a roadmap.

14 SPECIAL MASTER VANASKIE: Thank you.

15 Mr. Harkins, I'll give you the final word if there's
16 anything else you'd like to say.

17 MR. HARKINS: Well -- and, Your Honor, not to --
18 another frivolous analogy, but to the extent that this is
19 simply a recipe for baking a cake, Teva's internal recipe for
20 putting together a product or conducting an investigation or
21 implementing its own policies is Teva's recipe. It is
22 sensitive to us. We believe that it would cause competitive
23 harm to allow that specific recipe that Teva employs to be
24 disclosed.

25 Having said that, we understand Your Honor's

1 thoughts.

2 SPECIAL MASTER VANASKIE: Okay. Thank you all very
3 much.

4 If there's nothing else, we'll conclude for the day.

5 Is there anything else from anybody?

6 MR. HARKINS: Not from the defendants.

7 MS. HILTON: Not from me, Your Honor.

8 SPECIAL MASTER VANASKIE: All right. Thank you all
9 very much. Take care.

10 THE COURT: Thanks everybody. Happy New Year.

11 RESPONSE: Happy New Year.

12 (Proceedings concluded at 2:22 p.m.)

13 - - -

14 I certify that the foregoing is a correct transcript
15 from the record of proceedings in the above-entitled matter.

16

17 /s/ Ann Marie Mitchell 5th day of January, 2024

18 Court Reporter/Transcriber Date

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